Removing the cloud from industry-sponsored, multicentered clinical trials

It has been said that laws are imposed on 99% of the population to help prevent the improprieties of the remaining 1%. Although we like to think that the scientific process is exacting, rigorous, and honorable, unfortunately our community also needs oversight. Over the past 4 years as Editor-in-Chief of *Blood*, I have witnessed an alarming increase in the incidence of scientific misconduct, including the complete fabrication of papers, plagiarism of data or of insightful discussions, simultaneous submissions, and duplicate publications. Some misconduct is pernicious, for example, unnecessary delays by reviewers in order to allow their own work to gain precedence, or "anonymous tips" of investigator misconduct, which are as thoroughly investigated as possible but, on occasion, are actually attempts to discredit the work of competitors. Let me again emphasize that scientific misconduct remains rare but extremely worrisome and has led to many manuscript submission rules and regulations that are, at best, bothersome. The Roman historian Tacitus said, "The more the laws, the more corrupt the society." Although I do not believe that scientific and clinical data reporting should be termed corrupt, our community is faced with another form of abuse or potential abuse, the nontransparent evaluation of data in large, industry-sponsored, multicentered clinical trials of pharmacologic agents; it appears time to articulate another "law."

While sitting in a scientific meeting several years ago, I noted that the slides for 3 consecutive reports of clinical trials of a new therapeutic agent, presented by investigators from 3 separate academic institutions, utilized precisely the same format, font, color scheme, and computer graphics program. Afterward I found out that this was not coincidence; the pharmaceutical company sponsoring the trials had taken the raw data from the investigators, analyzed it, and then provided the slides for presentation. Many of us have witnessed similar instances in scientific publications. On numerous occasions, the lead author has not written the paper bearing his/her name; ghostwriters working for the pharmaceutical company sponsoring the trial have actually penned much of the manuscript based on the company's internal analysis of the primary data collected from the clinical investigators at participating academic medical centers. How has such a system of ghost-analysis and ghostwriting in multicentered therapeutic clinical trials come into being? This is apparently the way some in the pharmaceutical industry design their studies, a process enforced by the threat of withdrawal of future financial support for clinical trials. Unfortunately, there are many well-known examples of gross abuse of the practice, where the results of clinical trials have been "spun" into the best possible light or buried. Nevertheless, the industry, through the Pharmaceutical Research and Manufacturers of America, justify the ghostwriting and ghost-analysis processes, stating that examples of proven indiscretions are rare, that academic researchers are given the opportunity to review and make suggestions on such manuscripts, and that the academic investigator is too busy to take the time needed to create the publication. This is ludicrous; I would argue just the opposite. Clinical investigators, especially those early in their careers, need the experience of analyzing the primary data in clinical trials and preparing the results for publication; being handed processed data and a manuscript is hardly a formula for the successful development of creative investigators of clinical medicine. Moreover, we need to know that all clinical researchers have full access to all the data if we are to have confidence in the results of these analyses.

It is the view of the Editors that clinical investigators need the support of journals such as *Blood* to offset the potential pressures that can be brought to bear in their interactions with pharmaceutical companies, and the readership of *Blood* deserves to know that the data from a clinical trial published in the Journal have been scrutinized by both the scientists at the sponsoring pharmaceutical company and the academic investigators who contribute their clinical expertise to the study. Therefore, *Blood* now requires that in order for clinical trials to be published in the Journal, the lead author must be given access to all primary data on which the clinical study is based and must take responsibility for the preparation of the report. Without verification that such access has been granted, we will not consider publication of the work.

Having now better articulated this policy, we also recognize that we cannot relax our guard; maintenance of scientific integrity requires constant vigilance by both commercial and academic investigators. It is hoped, however, that by helping force the analysis of industry-sponsored clinical trials to become more transparent, this new policy might make scientific misconduct less likely. It might also help remove the shadow of mistrust in the scientific community which past abuses and present practices have helped to create. The editors believe that this approach is ultimately in the best interests of academic institutions and their investigators, pharmaceutical companies, and the public health.

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